Application No. 09/786,435
Filed: March 20, 2001
TC Art Unit: 1645
Confirmation No.: 1324

REMARKS

Claims 1, 5-8 and 11-18 were pending in the present application. Claims 1, 5, 16 and 18 are amended herein. Accordingly, claims 1, 5-8 and 11-18 will be pending upon entry of the instant amendments.

Support for the amended claims can be found throughout the specification and encompassed by the scope of the claims as originally filed. In particular, support for the amendment to claims 1 and 5 can be found, at least, for example, on page 2, lines 5-7, and on page 2, line 31, to page 3, line 6, of PCT WO 00/13705 specification. Additionally, support for the amendment to claim 5 may be found, at least, for example, on page 3, lines 25-28 of the specification. The amendment to claims 16 and 18 are made to correct claim sentence structure and proper dependency. No new matter has been added.

Any amendments to the claims should in no way be construed as acquiescence to any of the Examiner's rejections and were done solely to expedite the prosecution of the application. Applicant reserves the right to pursue the claims as originally filed in this or a separate application(s).

The Examiner asserts that Applicant's previous Amendment was not entered because the currently amended claim 5 would require further consideration and new searches. Applicant respectfully disagrees.

Applicant would like to point out that the scope of claim 5 as originally claimed included a pharmaceutical composition comprising a first compound (capable of substantially inhibiting the biological activity of TGF-β on predamaged neurons) and a

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second compound (for disintegrating blood clots) and to a pharmaceutical composition comprising the first compound, the second compound and optionally a pharmaceutically acceptable carrier and/or diluent (*cf.* page 3, lines 25-28, of the specification). Whereas, the scope of the amended claim 5 relates only to a pharmaceutical composition comprising the first compound, the second compound and a pharmaceutically acceptable carrier. Plainly, the scope of searching parameters would have included having a pharmaceutically acceptable carrier even though the original claim recites "optionally," since "optionally" does indicate an inclusion of a pharmaceutically acceptable carrier as well as its exclusion. Additionally, the scope of the original claim 5 also included a pharmaceutically acceptable carrier with or without a diluent. Accordingly, Applicant considers that the amended claim 5 does not require a new search and is not considered to raise new issues.

Claim Rejections - 35 U.S.C. §102

Claims 1, 5-8, 11-13 and newly presented claims 14-15 and 18 remain rejected under 35 U.S.C. §102(b) as being anticipated by Logan et al. (WO 93/19783). The Examiner asserts that Logan et al. teaches "the use of anti-TGF-β antibodies and the TGF-β antagonists in a method of inhibiting the biological activity of TGF-β."

Applicant respectfully traverses the rejection. The Examiner's Advisory Action was not responsive to Applicant's previous arguments regarding the foregoing rejection.

The claimed invention, as currently amended, includes the step of providing a patient having a cerebral disorder that results in predamaged neurons (claim 1). The method of the

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invention treats the predamaged or injured neurons with a compound inhibiting the biological activity of TGF-β.

Logan et al. is distinguishable from the presently claimed invention. Logan et al. fails to anticipate requiring a patient having a cerebral disorder that results in damaged neurons. Logan et al. uses different method steps and is absolutely silent with regard to treating predamaged neurons in a manner that can prevent neuronal cell death. In contrast to the present invention, Logan et al. is directed to controlling scar formation developed by a deleterious accumulation in the extracellular matrix in a tissue of the CNS by contacting the tissue with an agent that inhibits the extracellular matrix producing activity of TGF-β. Not only is the pathology of the CNS injury treated by Logan et al. distinguishable from the present invention, but Logan et al. is also distinguishable in the targeting site of administration of the therapeutic compound (extracellular matrix vs. predamaged neurons). Applicant's invention solves a different problem and has a different approach from that of Logan et al., and such differences are recited in the claims. Logan et al. fails to anticipate each and every element of the claimed invention.

Additionally, in claim 5 and the claims dependent thereon, the pharmaceutical composition of the invention comprises not only a compound that inhibits the biological activity of TGF-β on predamaged neurons caused by cerebral disorders, but also a second compound for disintegrating blood clots, which are both formulated in a pharmaceutically acceptable carrier only. Logan et al. fails to anticipate each and every element of the claimed invention. Logan et al. is absolutely silent with respect to using a compound for disintegrating blood clots, or anticoagulants, in combination since Logan et al. is directed to pathologies characterized by a

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deleterious accumulation of extracellular matrix in a tissue. Logan et al. cannot anticipate the claimed invention.

Claim Rejections - 35 U.S.C. §103

Claims 1, 5-8, 11-13 and newly presented claims 14-18 remain rejected under 35 U.S.C. §103(a) as being unpatentable over Logan in view of Alexander et al.

Applicant respectfully traverses the rejection. The Examiner's Advisory Action was not responsive to Applicant's previous arguments regarding the foregoing rejection.

The independent claims as well as their respective dependent claims are considered allowable per the argument raised above addressing the primary reference Logan et al. Logan et al. fails to teach or suggest providing a patient having a cerebral disorder that results in predamaged neurons and also fails to teach or suggest treating the predamaged neurons from cell death by inhibiting the biological activity of TGF-β on predamaged neurons.

Alexander et al. fails to cure the deficiencies found in Logan et al. Alexander et al. describes treating blood clots. Alexander et al. fails to teach or suggest treating predamaged or injured neurons in cerebral disorders by inhibiting the biological activity of TGF-β (*see* page 2, lines 5-7, of WO 00/13705 specification). Neither Logan et al. nor Alexander et al. contains any suggestion that these be combined, or even that they could be combined, in the manner suggested. Logan et al. pertains to the accumulation of extracellular matrix in a tissue while Alexander et al. is directed to blood clots. One of ordinary skill in the art would not think of combining the teachings of Logan et al. with Alexander et al. since they are in different fields of medicine. No motivation is proffered with respect to

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such combination. Even assuming *arguendo* that the combination of Logan et al. with Alexander et al. does teach some aspects of Applicant's invention, it would not be obvious to a skilled artisan to come up with the invention because the invention is directed to a different patient population having different effects and conditions. There is nothing in Logan et al. to suggest using an anticoagulant for blood vessels in combination with a tissue therapy let alone any suggestion to teach using an anticoagulant in a treatment for predamaged or injured neurons in cerebral disorders. Applicant respectfully requests reconsideration and withdrawal of the foregoing rejection.

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CONCLUSION

Based on the foregoing, entry of the amendments and remarks presented herein, reconsideration and withdrawal of all the rejections and allowance of application with all pending claims are respectfully requested.

The Examiner is encouraged to telephone the undersigned attorney to discuss any matter that would expedite allowance of the present application.

Respectfully submitted,

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